

PROGRESS REPORT

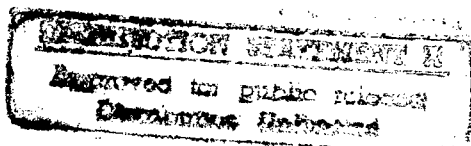
February 1, through February 28, 1997

OFFICE OF NAVAL RESEARCH GRANT NO:

N00014-95-1-0055

DTIC QUALITY INSPECTED 2

National Marrow Donor Program®
3433 Broadway Street N.E.
Suite 500
Minneapolis, MN 55413



April 14, 1997

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PROGRESS REPORT FOR OFFICE OF NAVAL RESEARCH

GRANT NO: N00014-95-1-0055

(As Modified through P00001, A00002)

This periodic progress report covers activities supported by Grant #N00014-95-1-0055, as modified, from February 1, through February 28, 1997. This Grant was due to expire on September 30, 1996. Amendment A00002 extended it through December 31, 1996. Amendment A00003 extended it through September 30, 1997. As only 12 budgeted line items will have activity, this report will be limited to those items in this report and in the future.

I. PROJECT DESCRIPTION

A. Specific Aims

During this period, the National Marrow Donor Program® (NMDP) used grant funds to support activities directed toward the following goals.

1. Enhance an already effective system which rapidly identifies and tracks the availability of matched donors for patients requiring marrow transplants.
2. Increase the total number and racial diversity of NMDP's volunteer donor file and provide HLA-DR typing on as many donors as possible in an effort to reduce patient search time and costs.
3. Perform HLA typing of the donor/recipient samples stored in NMDP's research sample repository, and compare the detailed molecular typing results with patient outcome data to determine the correlation between post-transplant outcome and degree of HLA match.

B. Budgeted Categories

1. **\$4,550,000 Scientific Studies of Allele-Specific Typing of Donor\Recipient Samples.**
2. **\$0 NMDP HLA Match Vs. Outcome Research (Reallocated)**
3. **\$16,477,798 Histocompatibility Laboratories for DNA HLA-DR Typing**
4. **\$24,000 Histocompatibility Laboratories for HLA-A, B & DR Typing**
5. **\$0 NMDP Staff Immunogeneticist (Reallocated)**
6. **\$553,625 Repository**
7. **\$600,000 Feasibility for Confirmatory Class I DNA Testing**

8. \$0 Contract Laboratory for Reference/Pre-Test Cells (Reallocated)
9. \$100,000 Class I Sequencing Database
10. \$915,671 Donor Center Hardware/Software
11. \$500,000 Facilitation of Rapid Communication with Foreign Registries
12. \$12,717 Probability of A, B, DR Identical Matches
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17. \$75,000 Donor HLA Override Modifications
18. \$0 Enhancements to BMDW Processing (Reallocated)
19. \$0 Cord Blood Repository Software (Reallocated)
20. \$0 Transplant Center Software (Reallocated)
21. \$0 Modify Repository Software (Reallocated)
22. \$11,425,000 Minority HLA-A, B Typing
23. \$67,833 National Minority Campaigns
24. \$300,000 Pilot Recruitment/Retention Program
25. \$6,250,406 Community HLA-A, B Matching Funds
26. \$5,859 Donor Center Waiting Lists
27. \$135,000 Physician Histocompatibility and Transplant Center Coordinator Education
28. \$972,291 Registry Wide Newsletter

- 29. \$0 Transplant and Collection Center Newsletter (Reallocated)
- 30. \$3,898 Physician Education
- 31. \$16,358 Patient Education
- 32. \$0 NMDP Speaker Support Materials (Reallocated)
- 33. \$479,599 Targeted Group Awareness and Education Activities
- 34. \$549,854 Integrated Communications for Targeted Campaigns
- 35. \$0 Phase II National Public Service Campaign (Reallocated)
- 36. \$256,989 Long Term Blood Storage Alternative Investigations
- 37. \$615,297 Program Administration
- 38. \$266,799 Alternative Blood Products Software

II. RESULTS BY CATEGORY

A. HLA Typing And Research

1. Scientific Studies of Allele-Specific Typing of Donor\Recipient Samples

This project's primary objective is to determine the impact of HLA matching, defined by the highest resolution of molecular typing possible, on transplant outcome. The project was initiated with funding from Navy Grant N00014-93-1-0658 and continues under funding from this grant. There are three phases to this study. Phase I continues the allele level class II typing on the donor-recipient samples stored in the NMDP's repository at Irwin Memorial Blood Center; Phase II entails obtaining allele-level class I typing on the donor-recipient samples; and Phase III involves data analysis and transplant outcome correlation.

Phase I

The nine laboratories involved in this phase of the project have now completed the typings of the first 1302 donor-recipient pairs funded under Navy grant N00014-93-1-0658. The level of resolution for continuation of this phase has been defined upon evaluation of competitive bids, 6 laboratories were selected to continue participation in this project. The new contracts and typing of 1,000 new donor recipient

paired samples began in December 1996. We will begin to receive results in January 1997.

Phase II

Samples were forwarded to participating contract laboratories during the months of November and December 1995. Typing of these samples is approximately 85% completed, and is expected to be completed by March. Results reported to date are detailed in Attachment 2. New contract amendments were executed on February 12 to type the next 1,500 pairs.

The NMDP will be responsible for the management of the data generated by the class I and II typing laboratories. Software and programming to manage the data and to make the necessary comparison was completed January 1996.

3. **Histocompatibility Laboratories for DNA HLA-DR Typing**

In February 1992, a DNA pilot project was implemented to test the feasibility of using DNA technology, specifically Polymerase Chain Reaction (PCR) Sequence Specific Oligonucleotide Probe (SSOP) typing to identify the class II antigens at the HLA-DR and DQ loci. An additional focus of the pilot project was to institute a quality control system which would monitor the performance of the laboratories and establish an accuracy standard for PCR-SSOP typing. The pilot project successfully demonstrated that prospective collection of HLA-DR samples for storage and later typing by DNA contract laboratories was an efficient option for prospective HLA-DR typing of large numbers of volunteer donors as well as for patient-directed typing. In addition, the blind quality control program has shown that molecular HLA-DR typing can be performed at high volume and low cost and still be highly accurate (less than a 2% error rate overall). The efforts of the pilot project were funded under Navy grant N00014-91-J-1895.

Based on the success of the DNA pilot project, the program was expanded (under funding provided through Navy grants N00014-92-J-1551 and N00014-93-1-0658) to include two DNA repositories, 16 contract DNA typing laboratories and all NMDP donor centers. The design of the DNA project remained virtually identical to that of the pilot project and continues to include ongoing quality control. Funding for these typings was provided through this Navy grant beginning on March 1, 1995. Prior to that time, Navy Grant N00014-93-1-0658 funded the typings for this project. Attachment 3A details the activities of these laboratories. During this reporting period the typing activities were funded through a contract between the NMDP and the Health Resources and Services Administration (HRSA).

6. Repository

The NMDP's two DNA repositories (American Red Cross National Headquarters and Children's Hospital of Pittsburgh) continued to receive samples from virtually all of the NMDP's donor centers. Approximately 90%-95% of all newly recruited donors have samples submitted to one of the two NMDP DNA repositories. Currently, repository services provided by the Children's Hospital of Pittsburgh are funded separately. The activity of the two repositories during the report period is detailed in Attachment 3B.

7. Feasibility for Confirmatory Class I DNA Testing

The technology of molecular HLA typing for identification of class I HLA types has progressed rapidly in the past few years. Although the technology is not as advanced as in class II HLA typing, it has progressed to the point where antigen-level typing can be performed by molecular means for the HLA-A and B loci.

The feasibility of developing a network of labs to perform DNA-based HLA-A, B typing, the impact on existing procedures and practices at the transplant centers and DNA repositories, and the costs associated with developing this network would be determined and used to evaluate whether network-wide implementation is possible. The benefit of utilizing molecular class I typing lies in the ability to perform a very accurate, detailed molecular typing on a stored sample, to confirm a questionable result or to implement confirmatory typing while the donor is completing other parts of the search process, such as the information session or physical exam. Either scenario would result in a shortened search process, because fewer discrepant samples would be identified in later stages of the search process. The ability to conduct confirmatory typing in parallel with other donor procedures would significantly shorten the search process, saving lives in those cases when the patient has little time to spare. An RFP was released November 1, 1996, to solicit proposals from laboratories capable of performing DNA-based HLA-A, B typing. Proposals from 35 laboratories were received by the December 13 due date. The technical review of these proposals was held February 20, 1997. Review of the Business Proposal will be completed and offer letters will be sent in March. Since the RFP was just released, no funds have been expended in this category to date.

B. Electronic Communication

1. Donor Center Hardware/Software

The conversion of STAR LinkTM to all domestic donor centers using DMAT has been completed. As of the end of November 1996, 78 donor centers were successfully converted to STAR Link.

2. Facilitation of Rapid Communication with Foreign Registries

The NMDP is working in cooperation with foreign registries to provide international data exchange and to streamline international searches. The STAR® system has been installed and is currently operating at the Australian Bone Marrow Donor Registry (ABMDR) in Australia. As of February 1997, requirements have been defined and programming completed for an upgrade of ABMDR's version of the STAR application. A duplicate of ABMDR's system has been set up at the NMDP to provide a test environment for the upgrade. As of January 1997, testing has begun on the new STAR release to the Australian Registry.

NMDP preliminary searches are sent electronically on a daily basis to the Anthony Nolan Bone Marrow Trust in England, who then returns a file of search results. A similar interface has been designed, developed and tested for France Greffe de Moelle (FGM). The NMDP began electronically sending preliminary searches to the FGM in July of 1996.

4. Revision of Search Algorithm

Although the STAR® system stores the DNA typing data for both donors and recipients, the current matching algorithm evaluates the match grade based upon serologic equivalent typing results. The NMDP Histocompatibility Committee addressed the need to revise the algorithm to incorporate molecular-based matching at its November 6, 1995, meeting. A working group of histocompatibility experts and transplant center physicians has been assigned to define the matching criteria. All the funding available for this project in N00014-95-1-0055 has been expended, however, effort continues under the Cooperative Agreement.

10. Cord Blood Repository Software

This category has been reallocated to \$0. Effort on this project has been delayed due to completion of other cord blood phases. These funds were reallocated in March 1996 to fund the Alternative Blood Products Software.

C. Donor Services Activities

3. Pilot Recruitment/Retention Programs

In 1993, the NMDP requested Navy funds to continue minority focused recruitment efforts after the targeted campaigns were completed. The goal was to develop models for each racial/ethnic group that would maximize the numbers of donors recruited onto the registry and also improve retention of these donors when they were contacted for further testing on behalf of a patient.

The NMDP seeks to build on previous programs funded by the Navy with special attention to those recruitment strategies and programs that

have proven to be most successful and appear to provide the greatest opportunity for replication in other areas.

A Request for Proposal (RFP) was let in the spring of 1995 to community based organizations and donor centers in selected geographic areas. The response was very low and determined not to be competitive. The Navy was asked to allow NMDP to redefine the use of the funds for this program for the following:

- Provide an opportunity for existing NMDP recruitment groups (8) that focus on minority recruitment to receive one recruitment staff position. The RFP was let in June 1996 with a response deadline of July 19, 1996. Four (4) recruitment groups were awarded subcontracts for a Coordinator for Minority Public Education/Awareness, based on proposals submitted and reviewed through June 1997.
- Provide staff support for the American Indian/Alaska Native initiative, especially for health professional education about unrelated marrow transplantation.

Remaining funds were reallocated out of this line item for community matching typings.

D. Public education and Awareness

4. Physician Education

NMDP presented a Symposium at the American Society of Hematology (ASH) annual meeting in Orlando, Florida on December 6, 1996. NMDP's was one of 21 selected by ASH. The Symposium "Donor Options and Stem Cell Choices: Transplant Considerations for the Patient without an HLA-identical Sibling" featured presentations from six researches and clinicians who addressed hematopoietic stem cell transplantation. They highlighted the outcomes of unrelated donor transplants, mismatched family transplants, cord blood transplants, and autologous transplants. The role of the minor histocompatibility antigens in transplantation as well as methods to overcome HLA disparity were also discussed.

This meeting is an excellent forum for the NMDP, as it draws over 12,000 attendees worldwide. NMDP plans to submit an application to ASH in February for the 1997 Symposium selection.

7. Targeted Group Awareness and Education Activities

C&E staff continues to create new opportunities to generate visibility in the media and help our local centers increase the potential success of events and activities designed to raise awareness of the need for volunteers, particularly minorities, to join the Registry.

Major media coverage during February included: Black Child, New York Times, Ivanhoe Broadcast News (a medical news supplier to 150 markets), CBS, TNN, New York Times, Information Television Network, New York Newsday, TV Interactive, and Auto Racing. Staff also worked with TBS on a documentary about bone marrow transplants. They will include one of the NMDP's PSAs and will run the 800 number. The air date for this program has not been announced.

Preparations are underway for the media blitz to release the Keep the Circle Strong Public Service Announcement. It will go out in time for pow wow season, which is a big recruitment time.

Network activities centered on Black History Month and Chinese New Year were featured on the NMDP website.

We continue to receive follow-up calls from minority media, especially Hispanic reporters, who received our materials at the National Association of Hispanic Journalists conference last year.

8. Integrated Communications for Targeted Campaigns

NMDP uses communications firms with cultural experience and resources specific to each targeted audience. The expertise of C&E and the firms enables development of culturally sensitive, campaign-specific materials in languages key to our audiences. These materials are tested among representative groups for cultural sensitivity and effectiveness. Additionally, the firms provide a resource with non-English speaking minority media.

Staff is working closely with the campaign markets and our hired communications firm Valencia Perez and Echeveste (VPE) to develop a plan for a series of media breakfasts. The events will serve as a vehicle for widespread distribution of the public service announcements and will be specifically designed to attract public service directors, as opposed to reporters. This will help our coordinators develop relationships with an important segment of the media audience they are not as familiar approaching and will help foster relationships that can lead to more consistent placement of PSAs in the future.

The Keep the Circle Strong T-shirt was printed this month. The T-shirt like all of the materials for this initiative has been very popular.

Copies of the television and radio Public Service Announcements were produced for distribution.

E. Long Term Blood Storage Alternative Investigations

A contract (#6030) with Coriell Institute for Medical Research was issued on March 1, 1995, to evaluate alternative methodologies of long term whole blood storage and to compare them with the current protocol of freezing whole blood in 1 ml aliquots. Based on less than satisfactory performance, this contract was terminated for convenience of the NMDP on November 7, 1995. An amount of \$6,989 was made to Coriell as complete payment for services performed. It is anticipated that the remaining funds will be utilized to fund a new study for alternative methods of long term whole blood storage.

F. Program Administration

During this period no funds were expended from this category to cover the salary, office rental, and related expenses of the Administrator, Navy Funded Programs. Attachment 1 reflects all approved reallocations.

III. SUMMARY

Navy grant # N00014-95-1-0055 continues to support NMDP projects which decrease the time and expense required for patients to find compatible unrelated donors, while funding research designed to increase understanding of the role of HLA matching on patient outcome post-transplant. Many of the activities described in this report represent continuations of successful projects implemented previously.

ATTACHMENT 1

\$45,000,000 NAVY GRANT
SUMMARY OF ACTIVITIES

NAVY GRANT N00014-95-1-0055 REALLOCATIONS REPORT

Category	Original Grant Budget	Added by Modification P00001	TOTAL MODIFIED GRANT AMOUNT	Reallocation *					#9 12/19/96	Total Reallocated Grant Amount
				#1 02/14/95	#2 06/06/95	#3 03/06/96	#4 05/10/96	#5 06/15/96	#6 09/06/96 (Verbally appd. 8/96)	
1 Scientific Studies of Allele-Specific Typing of Donor	\$3,100,000	\$1,450,000	\$4,550,000							\$4,550,000
2 NMDP HLA Match Vs. Outcome Research	\$500,000	\$0	\$500,000							\$0
3 Histocompatibility Laboratories for DNA HLA DR Typ	\$6,700,000	\$5,300,000	\$12,000,000					\$2,000,000		\$16,477,798
4 Histocompatibility Laboratories for HLA-A, B & DR T	\$2,300,000	\$500,000	\$2,800,000					(\$2,300,000)		\$24,000
5 NMDP Staff Immunogeneticist	\$200,000	\$200,000	\$400,000							\$0
6 Repository	\$700,000	\$700,000	\$1,400,000							\$553,625
7 Feasibility for Confirmatory Class I DNA Testing	\$0	\$300,000	\$300,000					\$300,000		\$600,000
8 Contract Laboratory for Reference/Pre-Test Cells	\$0	\$100,000	\$100,000							\$0
9 Class I Sequencing Database	\$0	\$100,000	\$100,000							\$0
10 Donor Center Hardware/Software	\$1,000,000	\$1,000,000	\$2,000,000					(\$100,000)		\$100,000
11 Facilitation of Rapid Communication with Foreign Regi	\$500,000	\$0	\$500,000							\$915,671
12 Probability of A, B, DR Identical Matches	\$50,000	\$0	\$50,000							\$500,000
13 Revision of Search Algorithm	\$200,000	\$0	\$200,000							\$12,717
14 Data Management for the International Consortium on t	\$250,000	\$150,000	\$400,000							\$200,000
15 HR/HW Search	\$0	\$0	\$0		\$34,680					\$211,326
16 Resolution of Discrepant HLA Typing on Donors	\$0	\$75,000	\$75,000							\$34,680
17 Donor HLA Override Modifications	\$0	\$75,000	\$75,000							\$0
18 Enhancements to BMDW Processing	\$0	\$100,000	\$100,000							\$75,000
19 Cord Blood Repository Software	\$0	\$150,000	\$150,000							\$0
20 Transplant Center Software	\$0	\$100,000	\$100,000							\$0
21 Modify Repository Software	\$0	\$75,000	\$75,000							\$0
22 Minority HLA-A, B Typing	\$4,400,000	\$5,750,000	\$10,150,000							\$0
23 National Minority Campaigns	\$250,000	\$750,000	\$1,000,000							\$11,425,000
24 Pilot Recruitment/Retention Program	\$1,000,000	\$500,000	\$1,500,000							\$67,833
25 Community HLA-A, B Matching Funds	\$2,100,000	\$2,300,000	\$4,400,000							\$300,000
26 Donor Center Waiting Lists	\$450,000	\$103,000	\$553,000							\$6,250,406
27 Physician Histocompatibility and Transplant Center Co	\$100,000	\$160,000	\$260,000							\$5,859
28 Registry Wide Newsletter	\$400,000	\$650,000	\$1,050,000							\$135,000
29 Transplant and Collection Center Newsletter	\$20,000	\$0	\$20,000							\$972,291
30 Physician Education	\$30,000	\$0	\$30,000							\$0
31 Patient Education	\$30,000	\$25,000	\$55,000							\$3,898
32 NMDP Speaker Support Materials	\$20,000	\$0	\$20,000							\$16,358
33 Targeted Group Awareness and Education Activities	\$150,000	\$0	\$150,000							\$0
34 Integrated Communications for Targeted Campaigns	\$550,000	\$0	\$550,000							\$479,599
35 Phase II National Public Service Campaign	\$0	\$50,000	\$50,000							\$549,854
36 Long Term Blood Storage Alternative Investigations	\$0	\$0	\$0							\$0
37 Program Administration	\$300,000	\$337,000	\$637,000							\$256,989
38 Alternative Blood Products Software	\$24,600,000	\$21,000,000	\$45,600,000							\$615,297
										\$266,799
										\$45,600,000

4/14/97
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* Date is the date of ONR Contracting Officer Written Approval to the NMDP

ATTACHMENT 2

**HIGH RESOLUTION CLASS I DNA
TYPING LABORATORIES**

CUMULATIVE DISTRIBUTION OF TYPING RESULTS
BY LOCUS
TOTAL FOR ALL LABS
February 28, 1997

LOCUS	RQSTD #	RESULTS COMPLETED		RESULTS OPEN		RESULTS PARTLY COMPLETED		RESULTS NOT COMPLETED		RESULTS NO MAKE	
		#	%	#	%	#	%	#	%	#	%
A	3003	2423	80.7	51	1.7	185	9.5	556	18.5	344	11.4
B	3000	2692	89.7	117	3.9	151	5.0	268	8.9	40	1.3
C	3000	2375	79.2	182	6.1	162	5.4	625	20.8	281	18.7
TOTAL	9003	7490	83.2	350	3.9	498	6.6	1449	16.1	665	7.4

RQSTD

= # of IDs that will be typed at a given locus

COMPLETED

= # of IDs where 2 valid results have been received

OPEN

= # of IDs where no results have been received

PARTLY COMPLETED

= # of IDs where 1 valid result has been received but the second result has not been received

NOT COMPLETED

= Sum of OPEN and PARTLY COMPLETE

NO MAKE

= # of IDs where a no make has been received at one or both alleles

ATTACHMENT 3

- (A) DONOR TYPINGS PERFORMED**
- (B) DONORS SAMPLES STORED AND SHIPPED**

NMDP DNA PROJECT**DONOR TYPINGS PERFORMED****February 1, 1997 - February 28, 1997**

PRIORITY 1	2,671
PRIORITY 2	9,884
PRIORITY 3	42

TOTAL	12,597
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NMDP DNA PROJECT**DONOR SAMPLES STORED****February 1, 1997 - February 28, 1997**

ARC - NATIONAL	12,791
PITTSBURGH	10,983

TOTAL	23,774
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DONOR SAMPLES SHIPPED**February 1, 1997 - February 28, 1997**

ARC - NATIONAL	6,540
PITTSBURGH	5,847

TOTAL	12,387
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